

NOTICE OF SERVICE: ATTACHMENT 1

**CONSOLIDATED REPLY MEMORANDUM
IN FURTHER SUPPORT OF PLAINTIFFS’
MOTIONS FOR PARTIAL SUMMARY
ADJUDICATION WITH RESPECT TO THE
CONTROLLED SUBSTANCES ACT
(DKT. #1910-1 & #1924-1)**

SUMMARY SHEET

In re National Prescription Opiate Litigation: MDL 2804
**CONSOLIDATED REPLY MEMORANDUM IN FURTHER SUPPORT OF PLAINTIFFS’
MOTIONS FOR PARTIAL SUMMARY ADJUDICATION WITH RESPECT TO THE
CONTROLLED SUBSTANCES ACT (DKT. #1910-1 & #1924-1)**

Summary Sheet of Concise Issues Raised

Motion Name: (1) Plaintiffs’ Motion for Partial Summary Adjudication of Defendants’ Duties under the Controlled Substances Act
(2) Plaintiffs’ Motion for Partial Summary Adjudication That Defendants’ Did Not Comply With Their Duties under The Federal Controlled Substances Act To Report Suspicious Opioid Orders And Not Ship Them

Moving Parties: Plaintiffs Summit County and Cuyahoga County

Concise Description of Issues:

Plaintiffs file this Consolidated Reply Memorandum in further support of their motions (1) for summary adjudication concerning the scope of Defendants’ duties under the Controlled Substances Act (“CSA”) and (2) for summary adjudication that Defendants failed to comply with those duties. Because the Defendants discuss both the legal and factual issues in their responses to both motions, for the convenience of the Court, Plaintiffs are submitting a single consolidated reply with respect to the two motions.

In their opening brief with respect to Defendants’ duties, Plaintiffs demonstrated that registrants under the CSA are obliged to maintain effective controls against diversion, to identify and report suspicious orders, and to halt shipment of each such order until it can be determined, through due diligence, that the order is not likely to be diverted. (The latter duty is sometimes referred to as the “no-shipping duty.”) In their opposition briefs, Defendants argue that the CSA and its implementing regulations do not impose any duties on registrants, much less a no-shipping duty. As a matter of statutory and regulatory construction, this argument is wrong: registrants are affirmatively required to maintain effective controls against diversion and there can be no effective controls if registrants are permitted to ship orders they know to be suspicious without first determining that the orders are unlikely to be diverted. In any event, the question whether these duties exist as a general rule is a question of law, ripe for adjudication on these summary judgment motions.

The duties to maintain effective controls against diversion and to identify and report suspicious orders are specifically mandated by DEA regulations, which have the force of law. The no-shipping duty has been recognized by the United States Court of Appeal for the D.C. Circuit and has been announced by the DEA in formal adjudications entitled to deference in this Court. The no-shipping duty is, in any event, a corollary of the requirement to maintain effective controls against diversion, because such controls cannot be effective if registrants are permitted to ship orders they know to

be suspicious without first investigating to determine that diversion is unlikely. Defendants' theory, that once they have identified suspicious orders to the DEA, they may wash their hands of concerns about diversion and carry on business as usual without regard to whether the narcotics they ship may be diverted is inconsistent with logic and with the regulatory scheme and should be rejected.

Defendants have further failed to create disputed issues of fact with regard to their compliance with the CSA (or lack thereof). In order to establish that summary adjudication is appropriate, Plaintiffs need not establish that Defendants were never at any moment in compliance. Rather, Plaintiffs need only establish that during portions of the relevant time period, Defendants failed to establish and maintain compliant programs. Thus, Plaintiffs need not prove the Defendants never identified any suspicious orders in order to establish, as a matter of law, that Defendants' SOM programs were not designed to identify—and were incapable of identifying—the full range of orders defined as suspicious by the CSA, and thus did not comply with Defendants' obligations. Similarly, Plaintiffs need not show that Defendants never halted a single suspicious order, if their evidence shows that Defendants routinely shipped such orders without due diligence and maintained no policy requiring due diligence before shipment. For this reason, Defendants' evidence suggesting that at particular time periods, or on specific occasions, they may have occasionally complied, does nothing to undercut Plaintiffs' undisputed evidence as to Defendants' massive and ongoing violations. What Defendants do not and cannot show is a factual dispute with respect to Plaintiffs' evidence that the SOM programs of each of the Defendants were materially and systematically defective (and indeed, in some instances, entirely non-existent) during relevant time periods, even if, on particular occasions, Defendants happened to meet the requirements of the CSA.

Defendants also dispute that adjudication of their violations of the CSA will streamline the trial and, in particular, dispute that their CSA violations constitute RICO predicate acts. But, as Plaintiffs pointed out in their opening brief, it is a predicate felony for anyone to manufacture, sell, or distribute controlled substances other than in accordance with the requirements of the CSA. Defendants' failure to comply with the statute and regulations, and thus to meet the conditions of their registrations, means that their manufacture, sale, and/or distribution of opioids was *not* in accordance with the statute and thus was felonious. Adjudication of this issue will thus streamline the presentation of evidence at trial, as certain of the elements Plaintiffs must prove will already be established.

Filing Date: June 28, 2019

Response Date: July 31, 2019

Reply Date: August 16, 2019